

FORM PTO-1390 (Modified)
(REV 11-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

ML-0486US

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/786901

INTERNATIONAL APPLICATION NO.

PCT/US99/20997

INTERNATIONAL FILING DATE

13 SEPTEMBER 1999

PRIORITY DATE CLAIMED

14 SEPTEMBER 1998

TITLE OF INVENTION

IMAGING OF SURGICAL BIOPSIES

APPLICANT(S) FOR DO/EO/US

James M. Zavislan and Roger J. Greenwald

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

Applicants hereby claim small entity status.

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 09/786901	INTERNATIONAL APPLICATION NO. PCT/US99/20997	ATTORNEY'S DOCKET NUMBER ML-0486US
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21. The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :					
<input type="checkbox"/>	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	\$1,000.00			
<input type="checkbox"/>	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	\$860.00			
<input type="checkbox"/>	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	\$710.00			
<input type="checkbox"/>	International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)	\$690.00			
<input checked="" type="checkbox"/>	International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)	\$100.00			
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$100.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	30 - 20 =	10	x \$18.00	\$180.00	
Independent claims	5 - 3 =	2	x \$80.00	\$160.00	
Multiple Dependent Claims (check if applicable). <input type="checkbox"/>				\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$440.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input checked="" type="checkbox"/>				\$220.00	
SUBTOTAL =				\$220.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				\$0.00	
TOTAL NATIONAL FEE =				\$220.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input checked="" type="checkbox"/>				\$40.00	
TOTAL FEES ENCLOSED =				\$260.00	
				Amount to be: refunded	\$
				charged	\$

- ☒ A check in the amount of **\$260.00** to cover the above fees is enclosed.
- ☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **50-1101** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

Kenneth J. LuKacher

NAME

38,539

REGISTRATION NUMBER

March 9, 2001

DATE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

Applicants: James M. Zavislan et al.
Serial No.: N/A
Filed: Concurrently herewith
For: IMAGING OF SURGICAL BIOPSIES
Examiner: N/A
Atty Docket: ML-0486US

Asst. Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-identified application as follows:

In the Claims:

Please rewrite Claim 11 as follows:

11. (amended) The system as set forth in Claim 8 wherein said scanning means further comprises an axial motion mechanism connected in driving relationship with a cassette, including said holder.

Please add new Claim 30 as follows:

30. The system as set forth in Claim 10 wherein said scanning means further comprises an axial motion mechanism connected in driving relationship with a cassette, including said holder.

REMARKS

Entry of the above amendments are requested for consideration by the Examiner. A marked-up version of Claim 11 is attached.

Dated: March 9, 2001

Respectfully submitted,



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APPENDIX

MARKED-UP VERSION OF AMENDED CLAIM 11

11. (amended) The system as set forth in Claim 8 [or 10] wherein said scanning means further comprises an axial motion mechanism connected in driving relationship with a cassette, including said holder.

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IMAGING OF SURGICAL BIOPSIES

This application claims the priority benefit of U.S. Provisional Application No. 60/100,179, filed 14 September 1998.

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Description

The present invention relates to imaging of biopsies (tissue specimens) and particularly to systems (methods and apparatus) for providing images of surgically removed tissue material from which images suitable for pathological examination, without delay for tissue preparation, such as freezing, sectioning, staining and mounting on microscope slides.

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Confocal laser scanning microscopes, such as the Vivascope® sold by Lucid, Inc. of Henrietta, New York, US and described in the Journal of Investigative Dermatology, Volume 104 No. 6, June, 1995, pp. 1-7 and International Patent Publication, WO-96/21938, published July 18, 1996, and in U.S. Patent No. 5,788,639, issued August 4, 1998 provide images of tissue sections on a patient which may be taken in vivo, without biopsy procedures taken. Pathological examination of these images can reveal the morphology of the tissue in a body region of interest rapidly and without the need for tissue preparation as conventionally used by pathologists. In many cases, such as in case of breast cancer examinations and treatment, tissue is excised, which is deeply disposed within the patient's body. Incisional or excisional biopsies may be taken by standard surgical methods - small needle core or large gauge cannular core. Incisions and excisions which are used for biopsies, either as biopsy samples or as excisional biopsies, which are intended to completely remove the abnormality, nevertheless must be examined so that the surgeon and pathologist can determine whether the biopsy sample has been taken in the location of the tissue of interest and whether the excisional biopsy has completely removed the abnormality. In such cases, pathological examination has delayed and extended the time for the surgical procedure to provide the biopsies. This is because of the time needed for preparation of tissue sections from biopsies to the pathologist for examination under a microscope. Such preparation procedures include freezing, sectioning, staining and mounting on microscope slides.

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The present invention enables the use of laser scanning confocal microscopy, such as described in the documents referenced above and other rapid electro-optical imaging

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techniques, such as optical coherence tomography (see, Optical characterization of disease tissue using low coherence interferometry, Proceedings of SPIE, Volume 1889 (1993)) and two photon laser microscopy (see, for example U.S. Patent 5,034,613 to Denk, et al., issued July 23, 1991), to be used to provide images of excised tissue, particularly biopsies. The electronic images produced by these imaging systems may be used by the pathologist to determine whether the biopsy has been successfully performed and the excision has been made in the proper location without the delay incidental to tissue preparation.

Briefly described, the invention may be carried out by encapsulating the tissue specimen, preferably during the excision procedure in an optically transparent carrier, such as a cassette, the walls of which confine the specimen under tension or compression. For the case of breast biopsies, the cassette is preferably made of a radiographic transparent material to allow for radiographic examination of breast biopsies. Radiographic examination verifies suspect breast tissue is inside the cassette. The cassette is then moved, preferably translated and rotated in azimuth about an axis through the cassette, while being scanned by an imaging system. The imaging system provides an electronic display of the surface of the tissue sample, as well as the volume adjacent to the surface. In addition, a mark or fiducial on the cassette indicates and corresponds to a position of the excision such that the image displayed contains information as to the location of the excised tissue material in the patient's body. No tissue preparation is necessary and the pathologist can determine from the display whether the excision is in the proper location as in the case of excisional biopsies, or has removed the abnormal material (e.g., the breast cancer nodule) entirely without leaving any apparently abnormal tissue in place.

The present invention has as its principal feature therefore, providing an improved system for the handling and imaging of biopsy samples which enable the use of electro-optical imaging techniques and to benefit from the facilities such techniques which provide for rapid and convenient pathological examination of biological tissue.

The foregoing and other features, objects and advantages of the invention will become more apparent from a reading of the following description in connection with the accompanying drawings in which:

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FIG. 1 is a schematic and block diagram of a system which enables electro-optical imaging of excised tissue samples, such as biopsies and the like with a confocal laser scanning microscope (CLSM); and

FIG. 2 is another schematic view illustrating the stage which manipulates an encapsulated sample in accordance with the invention.

Referring to the drawings, there is shown a confocal imaging system 10 which includes a head, in the case of a CLSM, containing an objective lens and is referred to as the objective lens 12. Associated with the confocal imaging system is a control system 14. This control system controls actuators associated with the objective lens 12, particularly an actuator 16 which moves the objective lens along a z axis, that is towards and away from the tissue specimen 18 and particularly the surface of the specimen 18, such that the focus of the confocal beam 20 can be advanced into and out of the specimen. In addition, the control system can control the motors and other actuation mechanism of a stage 22 by which the specimen 18 is manipulated. This manipulation includes the rotation about a longitudinal axis 24 (FIG. 2) and translation in a direction along the axis 24 by an axial motion mechanism 26.

Also associated with the confocal imaging system 10 is a display 28 on which an image of the specimen is obtained. The images can take the form of spiral projections of the tissue at a given depth at or below the tissue surface. This image can be produced by continuously translating the tissue cassette along axis 24 as the cassette rotates. The translation carries the cassette approximately one field of view for each complete revolution of the cassette. In this mode, the width of the image is set, by the field of view (FOV) of the confocal scan optics, at the focus of objective 12. The length of the image is $2\pi r L / \text{FOV}$, where r is the cassette radius, L is the length of the biopsy, and FOV is the transverse field of view. The second image representation is a vertical projection in which the objective lens 12 is scanned from the tissue surface into the tissue at a given rotational position and longitudinal position along axis 24. In this representation, the width of the image is the FOV and the height of the image is set by the scan depth. This image represents a vertical cross section of tissue morphology.

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Numerous vertical sections can be taken around the perimeter of the tissue to sample the biopsy surface. This image representation is analogous to standard vertical section pathologic preparation and examination.

Furthermore, a combination of imaging representations can be used. For example, portions of the tissue are surveyed with abbreviated or continuous spiral scans. Vertical sections can be scanned at various locations. The vertical section images can be combined with spiral projections to better represent the morphology of the tissue biopsy. The image can map a sheet which extends substantially perpendicular to the external surface of the specimen, thus constituting a volumetric representation of the surface of the specimen 18 and the tissue adjacent thereto. This image therefore is useful in showing the morphology of the biopsy (excision or incision) to the pathologist and may direct further surgical procedures (biopsies) and indicate whether such further procedures are necessary.

The image to be displayed may be stored in a memory or image storage which may be disc or solid state memory 30 which obtains the information from the imaging system 10 and presents it for display on the image display 28.

The images need not be displayed on site where the imaging system 10 and the stage 22 are located, but may be connected by a remote link, such as a wire radio or fiber optic link, to a remote image display 32. Such remote imaging for examination of tissue is the subject matter of Zavislan et al., U.S. Patent No. 5,836,877, issued 11 November 1998.

The invention provides for the encapsulation of the tissue specimen 18 in a cassette (or canister) 34. This cassette is made of transparent material. A preferable cassette material is amorphous polyolefin, which is preferred because of its low birefringence. Such material is sold under the tradename Zeonex by the BF Goodrich Company of Akron, Ohio, US and is manufactured by Nippon Zeon Company, Ltd., their grade E-48R being suitable.

The cassette 34 is generally cylindrical and is closed at the ends by endcaps, one of which 38, is shown in FIG. 2. This endcap or the cassette itself has a mark or position fiducial 40 which may be a groove in the cap. This groove is aligned with an indicia on the incision site to provide a reference location on the image which is displayed so that the pathologist can relate the location of the image to the location of the excision on the patient's

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body. The fiducial may be scanned by the confocal imaging system. Alternatively, the fiducial 40 is referenced to an encoder 46 (FIG. 2) oriented with respect to the axial or azimuth drive which rotates the cassette 34. This rotation may be obtained by a motor 41 which drives directly or through a gear system to drive and support rollers 42 and 44. The encoder 46 has a reference mark which may be aligned in an exact/or correlated azimuth relationship with the fiducial. The position information is provided by the encoder to the control system 14 and also to the display 28, as well as being contained in storage 30. The display therefore provides position information referenced to the fiducial on the cassette 34 or cap 38 which is in turn referenced to the excision. For example, the excision may be attached to a removable ring which is adhesively connected to the skin. The ring may be marked with an indicium or fiducial which indicates a reference point on the excision. Indicium is indexed and aligned with the fiducial on the cassette 34 or cap 38 thereby providing the positional information either from the scanning of the cassette or by means of the encoder 46.

The alignment of the encoder 46 with the cassette 34 may be carried out by means of a flange 48 attached to and rotatable with the motor shaft 50. The flange may be rotated with respect to the cassette 34 and cap 38 about the axis 24 and then attached to the cap by suitable fasteners which provide a sufficient mechanical coupling between the motor and the cassette. The encoder is thereby aligned by aligning its reference mark (usually on the surface of the encoder) with the reference mark or fiducial 40 on the cassette 34 or cap 38.

The rotational drive for the cassette 34 may be by means of the drive and support rollers 42 and 44, which rotate in the same direction, as indicated in FIG. 1 by the arrows adjacent thereto. This provides for rotation of the cassette in direction of the arrow 50 as shown in FIG. 1. While the cassette is rotating, the axial motion mechanism 26, which may include a lead screw mechanism, provides for movement along the axis such that the scan follows a corkscrew or helical path. The image is made by reflections from the focus of the confocal beam. This focus may oscillate inwardly and outwardly so as to trace a sheet which represents about 80% of the volume at and adjacent to the surface of the specimen 34. Alternatively, instead of an axial motion mechanism 26, the guide rollers may have a helical

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or screw-type surface so that the rotation thereof will provide axial motion of the specimen cassette 34. Various other means for axial and rotational motion to provide a helical scanning path may also be adapted for use in the stage 22.

In order to provide for matching of the index of refraction of the tissue sample, an index matching liquid 54 may be used in a container or tank 58 of the stage 22. The index of the cassette 34 may match the index of the tissue material in the cassette. In addition, the index of the liquid 54 may match the index of the material of the cassette. The index matching fluid may for example be a water solution which has an index of approximately 1.33. The slight difference in the index of the tissue and the cassette which provides for optical aberration (for example, astigmatism because of the cylindrical geometry), may be corrected, if found objectionable by the pathologist, by means of a correction lens in the objective lens unit 12 or by changing the refractive index of the matching liquid 54.

A tissue preservation fluid such as saline or other suitable tissue preservative fluid is inside the cassette 34 with the tissue 18 to ensure that no air bubbles are between the tissue and the cassette's inner surface.

The tissue specimen is excised and encapsulated in the cassette 34, preferably as part of the excision or biopsy procedure as carried out by the surgeon. In order to provide the transparent cassette 34, the trocar which is used to make the excision may provide the cassette 34. Alternatively, a conventional instrument for making the excision, such as shown in Ratcliff, U.S. Patent No. 5,709,697, issued January 20, 1998, may be used. The excision is held under tension by a corkscrew member of the instrument and may be deposited into the cassette and removed. The cassette may be part of a cannula through which the excision instrument is inserted. The cassette may be the outer part of the cannula and may be connected thereto as by a bayonet quick release connection. The cassette is the same size or slightly smaller than the excised tissue specimen and is held in the cassette. The endcaps are placed on the cassette after excision. The cassette may be closed at one end and capped at the other. In order to keep the tissue moist, a sponge/gauge pad, impregnated with saline or other suitable tissue preservative fluid, may be contained in the cassette, preferably at an end thereof and held in place by the cap.

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Modifications and variations in the herein described method and system will undoubtedly suggest themselves to those skilled in the art. Accordingly, the foregoing description should be taken as illustrative and not in a limiting sense.

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Claims

1. A system for imaging biopsy tissue which comprises means for encapsulating an excised tissue specimen in compression in a transparent holder, and means for scanning said holder and providing an image of the tissue specimen suitable for pathological examination.
2. The system as set forth to Claim 1 wherein said imaging providing means is a confocal imaging system.
3. The system as set forth in Claim 1 wherein said imaging system includes a stage in which said encapsulated specimen is moved during imaging.
4. The system as set forth in Claim 1 wherein said scanning means comprises a stage for translating and rotating said holder.
5. The system as set forth in Claim 2 further comprising an imaging system for providing said image, said system including a head via while illuminating radiation is made incident on said specimen in said holder, and means for moving said head at least in a direction toward and away from said holder.
6. The system as set forth in Claim 1 further comprising a stage for moving said holder included in said scanning means, said stage being disposed in a container in which optical coupling fluid is contained adjacent said holder.
7. The system as set forth in Claim 1 wherein said holder is a trocar.
8. The system as set forth in Claim 1 wherein said holder is a shell said scanning means including means connected to said shell for rotating said shell about an axis, and means

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engagable with said shell or a support, which constrains said shell to rotate about said axis, for translating said shell along said axis.

9. The system according to Claim 8 wherein said shell is a hollow generally cylindrical tube through which said axis extends.

10. The system as set forth in Claim 8 wherein said rotating means is a motor, said support is a pair of rollers on which said shell bears, said rollers having axes paralleling said axis, said motor being connected in driving relationship with said shell directly or via said rollers.

11. The system as set forth in Claim 8 or 10 wherein said scanning means further comprises an axial motion mechanism connected in driving relationship with a cassette, including said holder.

12. The system as set forth in Claim 11 wherein said rollers have helical or screw shaped surfaces in contact with said shell for providing translation thereof along said axis.

13. The system as set forth in Claim 1 wherein said scanning means provides a scan which follows a helical path.

14. The system as set forth in Claim 13 wherein said helical path traces a sheet through a volume of said specimen.

15. The system as set forth in Claim 1 further comprising means for providing alignment of said specimen with an indicia or fiducial mark on said holder, and means for referencing said image with respect to said mark.

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16. The system as set forth in Claim 15 further comprising an encoder coupled to said holder for providing signals correlated positionally with said scanning means.

17. The system as set forth in Claim 1 wherein said holder is a cassette of material substantially free of bi-refringence.

18. The system of Claim 17 wherein said material is amorphous polyolefin.

19. A method for imaging of surgical biopsies which comprises the steps of making an incision or excision in tissue of a body to provide a tissue specimen, encapsulating said specimen under compression in a transparent cassette, scanning said cassette to provide image for pathological examination of said specimen.

20. The method of Claim 19 comprising the step of making said incision with a trocar which provides said cassette.

21. The method of Claim 19 comprising rotating and translating said cassette with respect to a head of an imaging system to carry out said scanning step.

22. The method of Claim 19 further comprising the step of marking said cassette with an indicia or fiducial mark with respect to which said image is located.

23. The system as set forth in Claim 1 wherein said imaging system is operative in accordance with one of optical coherence tomography and two-photon microscopy.

24. A system for imaging a tissue sample comprising:
means for encapsulating the tissue sample in a cassette;
means for scanning the cassette to provide at least one image of the tissue sample suitable for pathological examination.

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25. The system according to Claim 24 further comprising means for moving said cassette with respect to said scanning mean.

26. The system according to Claim 24 wherein said cassette is of a material optically transparent to said scanning system.

27. The system according to Claim 24 wherein said scanning means is operative in accordance with one of confocal microscopy, optical coherence tomography, and two-photon microscopy.

28. An apparatus for enabling imaging of tissue held in a cassette by an optical imaging system capable of producing images of microscopic tissue sections of the tissue, said apparatus comprising:

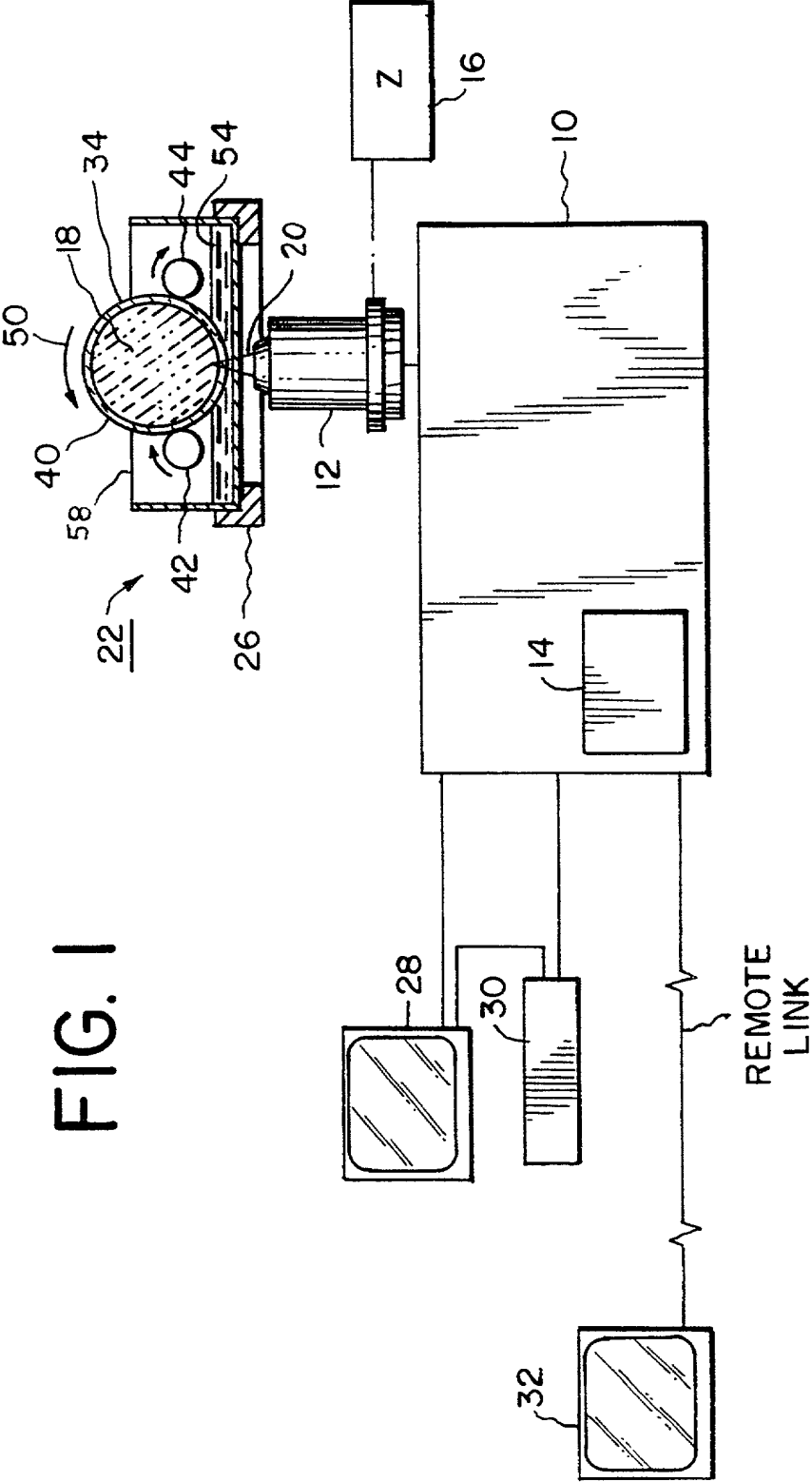
a stage which presents the tissue in the cassette to the optical imaging system; and
means for moving said cassette along a path with respect to the optical imaging system to enable microscopic imaging of the tissue in the cassette.

29. A cassette suitable for containing tissue excised from the body of a patient to present the tissue to an imaging system comprising:

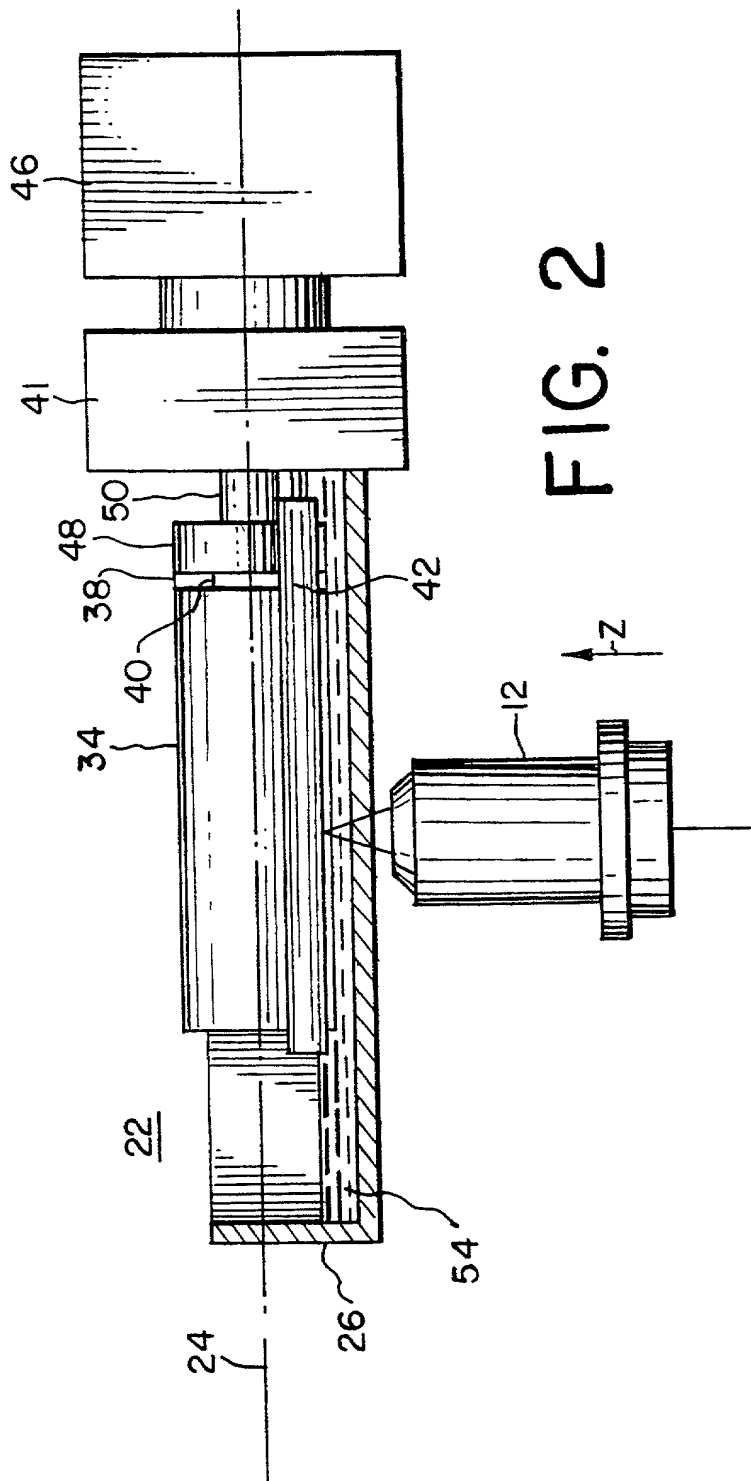
a cylindrical chamber capable of containing an excised tissue specimen;
said chamber being made of a transparent material and having at least one end cap; and
at least one fiducial on said chamber for referencing the position of the tissue in the chamber with respect to the body of the patient.

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FIG. 1



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Docket No.
ML-0486

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

IMAGING OF SURGICAL BIOPSIES

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on 13 September 1999 as United States Application No. or PCT International Application Number PCT/US99/20997 and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>

<u>60/100,179</u>	<u>14 September 1998</u>
(Application Serial No.)	(Filing Date)
<u> </u>	<u> </u>
(Application Serial No.)	(Filing Date)
<u> </u>	<u> </u>
(Application Serial No.)	(Filing Date)

PCT/US99/20997	13 September 1999	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

2 Kenneth J. LuKacher, Registration No. 38,539

Martin LuKacher, Registration No. 17,788

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Kenneth J. LuKacher - (716) 424-2670

Full name of sole or first inventor	<u>James M. Zavislan</u>
Sole or first inventor's signature	<u>James M. Zavislan</u> Date <u>7 March 2001</u>
Residence	<u>5 Wandering Trail, Pittsford, New York 14534 NY</u>
Citizenship	<u>United States of America</u>
Post Office Address	<u>Same as above</u>

Full name of second inventor, if any	<u>Roger J. Greenwald</u>
Second inventor's signature	<u>Roger J. Greenwald</u> Date <u>2-23-01</u>
Residence	<u>9385 Star Gaze Avenue, San Diego, California 92129 CA</u>
Citizenship	<u>United States of America</u>
Post Office Address	<u>Same as above</u>